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Target Article

Ethical Implications of Implantable Radiofrequency Identification (RFID) Tags in Humans

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This article reviews the use of implantable radiofrequency identification (RFID) tags in humans, focusing on the VeriChip (VeriChip Corporation, Delray Beach, FL) and the associated VeriMed patient identification system. In addition, various nonmedical applications for implanted RFID tags in humans have been proposed. The technology offers important health and nonhealth benefits, but raises ethical concerns, including privacy and the potential for coercive implantation of RFID tags in individuals. A national discussion is needed to identify the limits of acceptable use of implantable RFID tags in humans before their use becomes widespread and it becomes too late to prevent misuse of this useful but ethically problematic technology.

Keywords: radiofrequency identification, RFID, privacy, medical records

Tens of millions of animals have been implanted with radiofrequency identification (RFID) transponders for purposes of identification, and in increasing numbers these devices are being implanted in humans as well. The time is appropriate to consider some of the ethical issues and possible ethical limits to the use this technology.

RADIOFREQUENCY IDENTIFICATION (RFID) TECHNOLOGY

RFID technology employs transponders, also called *tags*, which are placed on or within objects. Remote readers using radiofrequency signals can interrogate these to yield information ranging from simple identification codes to detailed information about the object on which the tag is placed. The tags can be active (emitting signals powered using a built-in battery) or passive (using energy from the reader to activate circuits that transmit information to the reader).

Medically important applications of RFID technology include tracking drugs as they move through distribution channels (to help identify counterfeit or stolen drugs) and identifying patients by means of RFID tags embedded in wristbands (to help prevent errors in treatment). These applications employ tags located outside the body and are not of concern in this article.

Technology is well advanced as well for implanting RFID tags within the body (Troyk 1999). Implantable RFID tags are widely used in identifying farm animals, thoroughbred horses, household pets, and other animals, for health or nonhealth reasons. A few countries (Australia, New Zealand) have national livestock identification programs using microchips, in part to facilitate traceability of meat supplies; Japan requires dogs and cats brought into the country to be identified with a microchip. In addition, countless people have had their pet dogs and cats implanted with microchips for identification purposes, and one can even buy “cat flaps” that read the identification number of the cat’s chip and control a gate to allow it to enter and leave a house. Several firms service this large and rapidly growing market for implantable (in animals) RFID systems, and international standards are in place to ensure compatibility of readers.

The first implantable RFID system for humans to reach the market was developed by the Digital Angel Corporation (South St. Paul, MN), a manufacturer of RFID tags used in pets and livestock, and by its wholly owned subsidiary VeriChip Corporation (Delray Beach, FL). The system uses a passive transponder approximately the size of a grain of rice, which is injected beneath the skin in the posterior upper right arm. When exposed to magnetic fields from the

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Faced with disappointing sales, in July 2008 VeriChip sold its main operating division, and it is presently searching for a buyer for VeriMed (the implantable RFID portion of the business). (Personal communication (email) from Allison Tomek, Vice President, Investor Relations and Corporate Communications, VeriChip Corporation, to K. R. Foster, Aug. 8, 2008). See also the company’s press release dated July 18, 2008 available on the Internet at <http://www.verichipcorp.com/news/1216390353>.

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reader, the chip powers itself up and repeatedly transmits a unique 16-digit identifying code back to the reader. The chip communicates in one direction only, without listening for an acknowledgment from the reader, and its signal can be read up to a distance of tens of centimeters using a company-supplied reader.

In 2004, the United States Food and Drug Administration (US FDA) classified the VeriChip Health Information Microtransponder System as a class II medical device, clearing its way to market. The system is now aggressively promoted by VeriChip Corporation and is finding limited use in the United States and elsewhere.

The VeriChip Corporation is promoting its system, which it calls *VeriMed*, for use by patients who might present to healthcare facilities unresponsive and unable to provide identification. Obvious candidates include patients with Alzheimer's disease or severe mental illness, but the company's promotional literature mentions also patients with coronary artery disease, chronic obstructive pulmonary disease, diabetes mellitus, seizure disorders, cognitive impairment, who have suffered a stroke, or patients with complex medical device implants such as pacemakers, stents, or joint replacements (VeriMed 2007a).

As the system is presently marketed, a patient pays a physician approximately \$200 to have a chip implanted, and then subscribes to a data registry administered by the company, at a cost ranging up to approximately \$100 a year (VeriMed 2007b). Depending on the plan the customer chooses, the registry may include contact information for a patient's healthcare providers, links to a medical facility's electronic records system, and "advance directives" including a living will, power of attorney, name of a healthcare agent, do-not-resuscitate request, and organ/tissue donor card. The company distributes chip readers gratis to hospitals so that they might routinely scan nonresponsive patients for an identifying RFID.

Other groups, not connected with VeriChip, are also developing applications using implantable RFID chips. In 2006, Thevissen and colleagues described the implantation of commercially available RFID tags in dentures or human molars for identification of human remains. In January 2007, investigators from Eastman Kodak Company (Rochester, NY) applied for a patent for an edible RFID tag, which could be used to monitor internal bodily events following the ingestion of medicine (Spoonhower 2007). In June 2007, the US FDA gave premarket approval under a US Food, Drug and Cosmetic Act section 510(k) submission to ClearCount Medical Solutions, Inc. for RFID (Pittsburgh, PA) implanted surgical sponges, to help prevent physicians from accidentally leaving sponges inside a patient during surgery.

Several nonmedical applications of implanted RFID chips have the potential for widespread application. VeriChip is promoting a system, VeriGuard, to control access of individuals to secure areas. Early adopters include the Attorney General of Mexico, who in 2004 with at least 18 of his staff had chips implanted to allow them to gain access to areas with sensitive data. One Ohio firm (apparently now defunct) reportedly implanted two employees with mi-

crochips to allow them to access secure areas (Walters 2006). The company is also promoting use of implantable RFID chips for transaction processing, in which the implanted chips serve a similar purpose as the RFID tags that many consumers carry for gasoline or other purchases. According to news reports, in a few trendy bars in the Netherlands, Spain, Scotland and the United States patrons can get "chipped" at the door when they enter, enabling waitstaff to recognize the patrons by name and electronically record their purchases.

Other more speculative applications have been suggested. In an interview on May 16, 2006, on Fox News Channel (a US television network) Scott Silverman, Chairman of the Board of VeriChip, proposed implanting chips in immigrants and guests workers, to assist the government in later identification. Shortly afterwards, President Alvaro Uribe of Colombia was quoted as telling a US senator that he would agree to require Colombian citizens to have RFID chips implanted before being allowed to enter the United States for seasonal work. VeriChip has reportedly been lobbying the US military to replace metal "dog tags" worn by soldiers with implantable RFID tags (Francis and Myers 2006).

In addition to this work undertaken for explicit commercial purposes, a few individuals are experimenting with new applications of implanted RFID chips. Probably the most visionary such experimenter is Kevin Warwick, professor of cybernetics at the University of Reading (Reading, United Kingdom). In 1998 he had an RFID chip implanted as part of what he calls *Cyborg I Project* and could move about the halls of his university, operating doors, lights, and so on "without lifting a finger" (University of Reading 2005). According to Warwick's website, he in 2002 he had a microelectrode array implanted in the median nerve fibers of his left arm to allow him to develop a system that could send signals back and forth between his nervous system and a computer. A few hobbyists have had RFID chips implanted in their bodies in local tattoo parlors, and have develop circuits that will allow them to start their cars by waving their hands near a reader.

POSSIBLE MEDICAL RISKS

After having been implanted in tens of millions of animals, RFID chips would seem to pose few risks to humans; however, few humans have been implanted to date. In its ruling that classified the VeriChip as a class II device, the FDA listed potential hazards as:

adverse tissue reaction, migration of implanted transponder, compromised information security, failure of implanted transponder, failure of inserter, failure of electronic scanner, electromagnetic interference, electrical hazards, magnetic resonance imaging incompatibility, and needle stick" (US FDA 2004, 4).

The company's patient information sheet says that patients can "safely undergo MRI diagnostics," but there is only limited experience with such individuals. While implantation of a chip might be uneventful for most individuals, in the

experience of one of the present authors (a registered nurse with many years of clinical experience) there is no such thing as a minor procedure, particularly for elderly or frail individuals who may have thin, fragile skin and increased susceptibility to infection.

In recent months, a controversy has arisen about possible carcinogenic effects of implanted chips. This issue was not visibly part of premarket approval deliberations by the FDA of the VeriMed system, and was not discussed in publicly available statements by the company until it was raised in late 2007 by an anti-chip activist. In fact, for more than one decade it has been known that implanted RFID tags similar to those used in the VeriMed system are associated with tumors in rodents, mostly sarcomas (Blanchard et al. 1999; Elcock et al. 2001; Tillmann et al. 1997). The veterinary literature also contains a scattering of reports of tumors in dogs implanted with microchips (e.g., Vascellari et al. 2006). At least some of these investigators have attributed such effects to foreign-body induced tumorigenesis (Elcock et al. 2001), to which rodents are particularly prone, but which is not unknown in humans as well (Moore 1991).

ETHICAL ISSUES

Radiofrequency identification technology in general raises a number of important privacy and other issues, and a considerable literature exists on the subject (e.g., Ball and Wood 2006). Activists' websites have much discussion about possible harms from implanted RFIDs ranging from tracking of individuals to mind control. Using RFID technology to track individuals is already a reality, and products are on the market for such purposes. Conceivably, an individual might also be tracked via an implanted RFID tag, but that would be technically far more difficult because of the shorter read distance compared to an external RFID transponder. Mind control and other fears are, for the foreseeable future, in the realm of science fiction. Privacy is a generic issue with RFID technology.

There are, however, two areas of present ethical concern that are distinctive to implanted RFID chips, and in particular the VeriChip.

Disclosure of Risks

A central ethical principle holds that individuals have a right to know about possible adverse effects of a treatment, in this case implantation of a chip. Should VeriChip have disclosed the results of the rodent studies before anti-chip activists raised this issue? A finding of carcinogenic effect of an implant in rodents is, at least, suggestive of the possibility of a similar effect in humans.

Predictably, the issue has assumed major importance to VeriChip, which saw a large drop in its stock price following media reports of this issue. The company commissioned a consultant to write an article for its website that downplayed risks to humans. While regulatory agencies might not give much weight to indications of foreign-body induced tumorigenesis in rodents, there is clearly a diversity of opinion among experts. "I think the evidence from the animal stud-

ies is indeed alarming," one prominent cancer researcher told one of the present authors "and one should refrain from chipping people unless the mechanisms and long-term effects are known." (A. Lerchl, Jacobs University Bremen [Bremen, Germany], personal communication [e-mail] to K. R. Foster October 16, 2007). Should the possibility of cancer be added to the rather long list of potential adverse effects provided by the FDA, most of which are seemingly highly unlikely?

Truth in Advertising

VeriChip markets the VeriMed system for identification of patients who might present to emergency rooms incapable of communicating their identity to caregivers. Its promotional literature lists a wide variety of conditions, which, the company believes, would justify the cost of implantation of a chip and subscription to its medical database.

However, we know of no studies showing that being chipped gives a better outcome at the emergency room or otherwise improves public health in comparison with simpler and noninvasive technologies, such as medical alert bracelets, USB drives with personal health information, identification cards in wallets, fingerprint scanners, biometric identification, for example. An independent assessment of the risks and benefits of the use of implanted RFID tags in humans for medical identification purposes is badly needed, if only as a consumer protection measure to help consumers make informed decisions whether to buy into the system. For most individuals, we suspect, chipping would be a poor investment with slight prospects of resulting in a better outcome in a health crisis given other options available to the patient.

So far, only preliminary studies are underway which address this issue. A pilot project using this system was announced in June 2006 by VeriChip Corporation with Hackensack University Medical Center (Hackensack, NJ), a large provider of medical services in the state, and Horizon Blue Cross Blue Shield of New Jersey (Newark, NJ). A larger test, with 200 Alzheimer's patients, was announced in February 2007 by VeriChip Corporation and Alzheimer's Community Care, Inc (West Palm Beach, FL).

From the brief descriptions of these studies, it is not clear whether they are designed to assess benefits of the technology to individuals or to the healthcare providers. To make an informed choice, the consumer needs to know the likelihood that being chipped will result in a better outcome in a health emergency than with other identification technologies. A well-designed study to examine that endpoint would have to be far larger than either of the two studies mentioned previously. The pilot studies may be better suited to demonstrate the benefits to the healthcare system in accessing patient insurance and health records data, which is a different matter entirely. (The second of these studies raises issues of obtaining consent from Alzheimer's patients, a thorny bioethical issue in itself).

Given the uncertainties about the safety of implanted RFID chips, and uncertainties in the benefits that they may

bring, caution is warranted. We agree with the caution reflected in a recent report of the Council on Ethical and Judicial Affairs of the American Medical Association on the technology (Sade 2007):

Radio frequency identification (RFID) devices may help to identify patients, thereby improving the safety and efficiency of patient care, and may be used to enable secure access to patient clinical information. However, their efficacy and security have not been established. Therefore, physicians implanting such devices should take certain precautions: 1) The informed consent process must include disclosure of medical uncertainties associated with these devices. 2) Physicians should strive to protect patients' privacy by storing confidential information only on RFID devices with informational security similar to that required of medical records. 3) Physicians should support research into the safety, efficacy, and potential non-medical uses of RFID devices in human beings (4).

Coercion

If receiving an RFID tag were purely a matter of consumer choice, few serious ethical issues would arise apart from generic concerns about consumer protection. Thus, for example, a consumer might reasonably choose to be chipped—preferably not in a tattoo parlor—to avoid having to carry a credit card or RFID tag on a key chain.

By far the most important and distinctive ethical issues connected with implanted RFID transponders result from the very real possibility that the chips might be implanted under real or implied coercion, coupled with the deep aversion—or at least unease—with which many individuals view the technology.

Despite extensive, and at times hyperbolic, discussion of the uses of implanted RFID chips in humans to be found on the Internet, few systematic studies have been reported on the acceptability of implanted RFID chips to average people. A small survey in 2003 (Hiltz et al. 2003) found that 18 of 23 people questioned objected to the idea of implantable chips. "If they are putting something inside of you", one respondent replied, "it's like you're changing yourself. It's not right" (Hiltz et al. 2003, 7).

People from different cultures will certainly differ in their acceptability of implanted RFID chips. In some cultures, altering the bodily image may ostracize individuals from their sociocultural networks. In the United States, some fundamentalist Christian groups vehemently object to implanted RFID tags as "marks of the beast." Both Judaism and Islam prohibit tattoos, and their religious authorities may forbid implanted RFID tags for similar reasons. Other cultural and religious factors in acceptability of the technology have hardly been explored in discussions to date about implanting RFID chips in people for identification.

In view of widespread popular apprehension about the technology, proposals to "chip" individuals would raise extremely serious ethical issues if an element of coercion were involved, either direct or tacit. This can easily come about if RFID tags were to become widely adopted for access control or identification in nonmedical settings.

Indeed, a variety of proposals have been floated in public discussions that would involve coercive implantation of RFID chips, some on face value highly impractical. In March 2006, a columnist for *The New Republic Online* defended a proposal to implant RFID tags in sex offenders (Cottle 2006), pointing out that such people are already subject to extensive restrictions, and that tracking individuals through implanted RFID chips might be preferable to present practices, for example, residency restrictions based on Megan's Law legislation that in some jurisdictions force convicted sex offenders to sleep under bridges or in their vehicles. However, the proposal raises obvious objections on practical grounds. Must every entrance to every school be equipped with an RFID reader to detect chipped individuals? Would it not be easy for a chipped individual to conceal the transponder from the reader? A more practical way to implement the plan would be to chip the teachers instead, and use the RFID readers to provide positive identification when they enter a school. We suspect that teachers' unions would fiercely oppose such a plan.

Far more troubling (and thankfully very far from reality) is the proposal by Silverman (VeriChip's Chairman of the Board) to "chip" guest workers entering the United States. One might argue that receiving implants would be voluntary for such individuals. But which immigrant, facing poverty at home and the prospects of a job in a new country, would be in a position to argue with demands to have a chip implanted as a condition of entry into the country? Would college professors or bioethicists headed to the United States for a brief sabbatical or training be chipped as well as agricultural workers? If not, who would decide, and on what basis? If being chipped becomes a requirement for work by a noncitizen in the United States, what impact would there be on the global labor market? The prospects of being chipped will surely be a strong deterrent to others from coming here to work and learn.

Forcing immigrants to be chipped is deeply offensive on human rights grounds. It would frame the RFID chip as a branding device similar in theory to the brand of the western cowboy on cattle or to the tattoo of an inmate in a Nazi concentration camp. Arguably, it is a violation of Article 3 of the Universal Declaration of Human Rights (1948), which guarantees everybody the right to "life, liberty and security of person." To the extent that forced implantation of a RFID chip in a person's body is a violation of his/her privacy, it would also violate the privacy provision of the International Covenant on Civil and Political Rights (1966), to which the US is a party.

While implantable RFID technology is presently being marketed as a measure for patient protection, its chief benefit—convenient and reliable identification of an individual by means of a device that is difficult for the subject to lose—might well be more significant to organizations than to individuals, and the issue is intrinsically more complicated than one of consumer choice alone. In institutions that have adopted the use of implanted RFID tags for identification purposes, pressures will inevitably build on individuals to receive the tags. Suppose, for example, healthcare

organizations with electronic records systems gave their patients a choice between maintaining possession of an identification card or receiving a chip? Would elderly, forgetful patients be pressured to receive a chip? What about a soldier in an army that decided to replace dog tags with implanted chips? Are these individuals less vulnerable to coercion to receive a chip than the hapless immigrants considered in Silverman's proposal? Other technologies, such as fingerprint identification or retinal scans, allow reliable identification of individuals without the need to compromise bodily integrity.

Faced with widespread public concerns about coercive implantable RFID chips, several states have passed legislation regulating their use. In May 2006, for example, Wisconsin passed a bill (Assembly Bill 290) that would prohibit requiring anybody to have a microchip implanted. North Dakota and California have also passed similar bills. Enforcing such laws might be difficult if implanted chips, like drivers' licenses, remain legally voluntary but become de facto requirements for many kinds of employment, voting, or receipt of health care.

Because of concerns discussed previously, a national discussion is needed about the use of implanted RFID chips among the many groups potentially affected by the technology. Decisions about the use of the technology need to be made by a broader group of stakeholders than the engineers and companies involved in the field. A commitment must be made to restrict the technology to people who freely choose to be implanted, and to shield other individuals from real or implied coercion. As Anderson and Labay remarked (2006), a "decision about where to draw the line of acceptable use must be made soon, before the technology becomes rampant and it becomes too late to prevent misuse."

Or, in more specific terms, we have already implanted RFID tags in our dogs and cats. Is Aunt Millie next? ■

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